

## **Remarks**

The Office Action of May 6, 2010 has been carefully considered. Claims 1 - 7, 19 - 20, 22, and 24 - 25 are currently pending.

### **Claim Rejections - 35 U.S.C. § 102**

Claims 1 – 4, 19, 20, 22, and 24 - 25 are rejected under 35 U.S.C. § 102(e) as being anticipated by Parks, et al. (US Patent 7, 025,790 B2). This rejection is traversed.

The Examiner has misconstrued the pending claims and misconstrued the structure of Parks, et al.

First, the Examiner is treating the transition phrase "consisting essentially of" as equivalent to comprising. The Examiner indicates that "absent clear indication in the specification or claims of what the basics and novel characteristic actually are, "consisting essentially of" will be construed as 'comprising'." In this instance, both the Claims and Specification indicate what the basic and novel characteristics are. Accordingly, the transition phrase consisting essentially of should be construed correctly.

As indicated in the previous amendment, independent Claims 1 and 22 recite that the implant consists essentially of a monolithic structure. The term monolithic, by definition, clearly indicates that the implant is a single piece structure. The addition of the transition phrase, "consisting essentially of" clearly signals the exclusion of a structure that contains two or more pieces. Further, the Specification indicates that, "the implanted device is substantially free of anchoring portions that need to be

attached to the bone, cartilage, ligaments or other tissue." See Specification paragraph [0008]. Finally, each and every Figure clearly shows that the implant is a single piece structure. The claimed one piece implant that is structured to be implanted by itself without the need for additional components as is clearly evident from the Specification.

Parks, et al. does not disclose anything close to such a device.

Parks, et al. provides a two or three piece structure. Each piece works in conjunction with the other component.

The Examiner seems to believe that element 50 of Parks, et al. can be used without the other components disclosed in Parks, et al. The Examiner has no evidence whatsoever to form that belief and such a position is in direct contrast to the actual words and figures of Parks, et al.

For example Parks, et al. states:

FIG. 15 is a perspective, side view of a preferred, mobile bearing embodiment of the ankle joint prosthesis of the present invention. It consists of tibial 40, talar 50 and mobile bearing 60 components, where the tibial 40 and talar 50 components are mounted respectively on the prepared, crescentic-shaped tibial and talar surfaces. The mobile bearing component 60 is located between the tibial 40 and talar 50 components.  
See also FIG. 16. Parks et al. at col. 9, lines 38-45

In addition:

The mobile bearing component 60 has a flat top surface 62 and a saddle-shaped bottom surface 64. The bottom surface 64 is configured with a saddle-shaped configuration so as to match with the talar component's top surface 52 and to allow for internal and external rotation motions. This

saddle-shaped surface also allows for dorsiflexion and plantar flexion motion. Parks et al at col. 10, lines 25-30.

Next, the Examiner contends that the phrase "tibia being allowed to articulate across the first major surface" is functional and therefore not a structural limitation. The Applicants reminds the Examiner that the Claim was amended to recite that the first major surface is "shaped to allow the tibia to articulate across the first major surface." The term shaped clearly is directed to a structural limitation. That structural limitation is different from the shape of the talar component 50 of Parks, et al.

The talar component 50 of Parks, et al. is never in contact with the tibia. It is shaped to match the bottom surface 64 of mobile bearing part 60.

Finally, the Examiner completely ignores that the talar component 50 has 58 that extend downward from its bottom surface 54. The shape of these protrusions 58 is configured to match with the similarly shaped recesses or extrusions that have been made in the talar dome's prepared surface.

In contrast, the claimed monolithic structure is shaped such that, when implanted, the tibia can articulate across the first major surface of the monolithic structure. The monolith structure includes a bead shaped structure proximate to the implant's anterior side sized to engage the neck of the talus, wherein the implant is substantially free of anchoring portions for attachment to the tibia or talus. The talar component 50 of Parks, et al. has none of these features. The rejection should be removed.

Further Parks, et al. does not disclose a bead shaped structure proximate to the implant's anterior side sized to engage the neck of the talus. The Office Action cites to

col. 9, lines 61 - 63 of Parks, et al. However, the beads referred to in this section of Parks, et al. refer to material that is coated on the top surface of the tibial component (and therefore in contact with the tibia and not the talus) and is a substance that enhances bony ingrowth or cement fixation. These "beads" are entirely different functionally and structurally.

With regard to Claim 22, it recites the implanted device is substantially free of anchoring portions that need to be attached to the bone, cartilage, ligaments or other tissue. Parks, et al. does not disclose a device with this feature. The Examiner now claims that protrusions 58 of Parks, et al. are not anchoring portions because it is smaller than other anchoring portions. The Examiner ignores that these protrusions are large enough to actually fit inside recesses that have to be made in the surface of the talar bone. The idea that Parks, et al. does not have anchoring portions because its anchoring portions are smaller than other anchoring portions is not supported legally or factually.

With regard to Claim 25, as amended, it recites the monolithic implant comprises polyurethane that includes both hard and soft segments. Parks, et al. does not disclose a monolithic implant with this composition. Removal of the rejection is respectfully requested.

#### **Claim Rejections - 35 U.S.C. § 103**

Claims 5 – 7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Parks, et al. (US Patent 7, 025,790 B2) in view of Schon (US Patent 6,572,620).

For the reasons discussed above, Parks, et al. does not disclose the elements of Claim 1. Accordingly, the combination of Parks, et al. and Schon do not disclose the elements of Claims 5 - 7. Removal of the rejection is requested.

### **Conclusion**

The instant application is believed to be in condition for allowance. A Notice of Allowance of claims 1 - 7, 19 - 20, 22, and 24 - 25 is respectfully requested. The Examiner is invited to telephone the undersigned at (908) 722-0700 if it is believed that further discussions, and/or additional amendment would help advance the prosecution of the instant application.

If any extension of time for this response is required, applicants request that this be considered a petition therefore. Please charge any required petition fee to Deposit Account No. 14-1263.

Respectfully submitted,

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